

Dated: December 15, 1997.

John M. Eisenberg,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Assessment of Medical Technology

The Agency for Health Care Policy and Research (AHCPR), through the Center for Practice and Technology Assessment (CPTA), announces that it is initiating an assessment of the effectiveness of Prostate-specific antigen (PSA) testing in patients with benign prostatic hyperplasia (BPH).

The AHCPR is requesting information on the utility, and costs associated with the use of PSA testing and the specific indications for which this testing is appropriate. The AHCPR also requests information on patient selection criteria.

The assessment consists of a synthesis of information found in published literature and obtained from appropriate organizations in the private sector, Public Health Service (PHS) agencies and others in the Federal Government. AHCPR assessments are conducted in accordance with sections 904(b) and (d) of the PHS Act (42 U.S.C. 299a-2(b) and (d)). The assessment is based on the most current knowledge concerning the clinical effectiveness and appropriate uses of the technology being evaluated. The information being sought by this notice is a review and evaluation of past, current, and planned research related to this technology, as well as a bibliography of published, controlled clinical trials and other well-designed clinical studies. Information related to the characteristics of the patient population most likely to benefit from PSA testing as well as information on the clinical acceptability, effectiveness, and the extent of use of this technology, is also being sought. Following completion of the assessment, a recommendation will be formulated to assist the Health Care Financing Administration (HCFA) in establishing Medicare coverage policy.

The AHCPR is interested in receiving information which would help in the evaluation or review of the technology as described above. To enable the interested scientific community to evaluate the information and analysis included in the assessment, AHCPR will discuss in the assessment only those

data and analyses for which a source(s) can be cited. Respondents are therefore encouraged to include with their submissions a written consent permitting AHCPR "to cite and make public the sources of the data and the comments provided". Otherwise, in accordance with the confidentiality statute governing information collected by AHCPR, 42 U.S.C. 299a-1(c), no information received will be published or disclosed which could identify an entity or individual supplying the information or any individual or entity described in the information. In addition, clearly market proprietary information may be kept confidential in accordance with the Freedom of Information Act, 5 U.S.C. § 552(b)(4).

Any person or group wishing to provide AHCPR with information relevant to this assessment should do so in writing no later than March 23, 1998 to: Douglas B. Kamerow, M.D., M.P.H., Director, Center for Practice and Technology Assessment, Agency for Health Care Policy and Research, 6000 Executive Boulevard, Suite 310, Rockville, MD 20852, Phone: (301) 594-4015.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Number 816]

Individual Grants for Extramural Injury Research for Primary Prevention of Unintentional Injuries, Acute Care, Disability Prevention, and Biomechanics; Notice of Availability of Funds for Fiscal Year 1998

Introduction

The Centers for Disease Control and Prevention (CDC) announces that applications are being accepted for Injury Prevention and Control Research Grants for fiscal year (FY) 1998.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Unintentional Injuries. (To order a copy of Healthy People 2000, see the Section Where to Obtain Additional Information.)

Authority

This program is authorized under Sections 301, 391-394 of the Public Health Service Act (42 USC 241, 280b-280b-3), as amended. Program regulations are set forth in Title 42 CFR Part 52.

Smoke-Free Workplace

CDC strongly encourages all grant and cooperative agreement recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants include all nonprofit and for-profit organizations. Thus State and local health departments and State and local governmental agencies, universities, colleges, research institutions, and other public and private organizations, including small, minority and/or woman-owned businesses are eligible for these research grants. Current holders of CDC injury control research projects are eligible to apply.

Note: An organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible to receive Federal funds constituting an award, a grant, contract, loan, or any other form.

Availability of Funds

Approximately \$2.7 million is available for FY 1998 injury research grants that include funding for projects that address primary prevention of unintentional injuries (home and leisure, and motor vehicle related-injuries), acute care, the prevention of secondary conditions in persons with disabilities, and biomechanics.

Approximately \$1,800,000 is available to support 6-8 projects that address primary prevention of unintentional injuries (home and leisure, and motor vehicle related-injuries), acute care, and the prevention of secondary conditions in persons with disabilities. Awards will be made for a 12-month budget period within a project period not to exceed three years. The maximum funding level per year will not exceed \$300,000 (including both direct and indirect costs). Applications that exceed the funding cap of \$300,000 will be excluded from the competition and returned to the applicant.

Approximately \$900,000 is available to support 3-5 projects that address